

**G. Summary of Safety and Effectiveness - 510(k) Summary**

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The Surgiflator-20 PIM is a laparoscopic high flow insufflator intended to fill the abdominal cavity with CO<sub>2</sub> to enable laparoscopic procedures.

The Surgiflator-20 PIM described in this notification is similar in design and construction to the W.O.M. Surgiflator 20, K950035 and the Snowden-Pencer High Flow Insufflator, Model 89-8600 and Model SP 88-9700, distributed in the United States by Snowden-Pencer, Inc.

- The Surgiflator-20 PIM incorporates the same design features as the W.O.M. Surgiflator 20. The differences lie in the following features:
  - Low pressure insufflation mode - fills the abdomen more gently
  - Fluid sensor: shows the user when the device is contaminated by backflow
  - Simultaneous pressure monitoring: monitoring of the pressure directly in the abdomen
- The utility and safety of laparoscopic techniques using modern electronic high flow insufflators is thoroughly reported in the literature with the advantages and risks well articulated.
- A comprehensive discussion of the use of insufflation methods is presented in the book "Operative Laparoscopy" (1): 9-15, by M.-A. Bruhat, 1992, which observes that Laparoscopy, along with the entire concept of minimally invasive surgery through endoscopically guided intra-abdominal surgery, has become a mainstay in gynecologic surgery. The review of instrumentation in this field includes comments on the use of modern high flow insufflators, the establishment of the pneumoperitoneum, use of instrumentation and use of CO<sub>2</sub>-laser.
- Background information and experiences with the use of laparoscopic techniques including videoendoscopy are presented in the book "Minimal Invasive Surgery" (3): 57ff, 216-218, 291-295 by John G. Hunter, M.D. and Jonathan M. Sackier, M.D., McGraw-Hill, Inc., 3-6 and 216, 291. New technologies are discussed as well as advantages and disadvantages of minimally invasive surgery. The importance of effective, well-maintained instrumentation, i.e. insufflators and other instrumentation like light sources, television screens, and energy sources, is discussed.

**REFERENCES**

1. Maurice-Antoine Bruhat. "Operative Laparoscopy". New York: McGraw-Hill, 1992, 226 pages.
2. John G. Hunter. "Minimally Invasive Surgery". New York: McGraw Hill, 1993, 358 pages.